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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,543	09/29/2003	Masamichi Yanai	018961-064	6207

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EXAMINER
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HELLER, TAMMIE K

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/671,543		YANAI, MASAMICHI	
	<b>Examiner</b>		<b>Art Unit</b>	
	Tammie Heller		3766	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/29/03, 2/4/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 3-14 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding claims 3-7, applicant claims a "backflow detecting function", a "motor current threshold storing or calculating section", and a "backflow generation determining function", which do not constitute one of the four statutory classes of invention. The Examiner suggests applicant utilize means language or specify that the functions are performed by a computer readable medium or other hardware or software implementation. Further, regarding claims 4-7 it is unclear as to the exact process that is performed by the aforementioned functions.

Regarding claims 8 and 9, applicant claims a "backflow detecting function" which comprises a "motor current frequency distribution calculation function", and a "backflow generation determining function", which do not constitute one of the four statutory classes of invention. The Examiner suggests applicant utilize means language or specify that the functions are performed by a computer readable medium or other

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hardware or software implementation. Further, regarding claims 9, it is unclear as to the exact process that is performed by the aforementioned functions.

Regarding claims 10-14, applicant claims a "backflow detecting function" which comprises a "motor current derivative calculation function", and a "backflow generation determining function", which do not constitute one of the four statutory classes of invention. The examiner suggests applicant utilize means language or specify that the functions are performed by a computer readable medium or other hardware or software implementation. Further, regarding claims 11-14 it is unclear as to the exact process that is performed by the aforementioned functions.

Regarding claim 16, applicant claims a "rotational speed control function", which does not constitute one of the four statutory classes of invention. The examiner suggests applicant utilize means language or specify that the functions are performed by a computer readable medium or other hardware or software implementation.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claimed invention is indefinite and incomplete in that no positive structure is recited. Only functional language is present in

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the claim language. The examiner recommends replacing the word "function" with the word "element" or "means" to overcome this rejection.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakazeki et al. (U.S. Patent No. 5,725,357), herein Nakazeki. Regarding claim 1, Nakazeki discloses a magnetically suspended type pump which includes inlet ports 15 and 16, outlet ports 233 and 234, a rotor 22, and a motor 13 (see Figure 11A). Further, Nakazeki discloses detecting backflow based on a motor current function (see col. 1, ln. 47-49).

7. Regarding claim 2, Nakazeki discloses that there is no direct flow rate detecting means in the pump (see col. 1, ln. 38-43).

8. Regarding claim 16, Nakazeki discloses that the speed of rotation is controlled (either increased or decreased) in response to a correlation between the motor current and backflow detection (see Abstract and col. 5, ln. 55-57).

9. Regarding claim 17, Nakazeki discloses that rotor 22 is an impeller (see col. 6, ln. 49).

10. Claims 1, 2, and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Ayre et al. (U.S. Patent No. 6,866,625), herein Ayre. Regarding claim 1, Ayre discloses inlet port 6, outlet port 7, rotor 100, and motor 18 (see Figure 1 and 2). Further, Ayre discloses a backflow detecting function (see col. 6, ln. 28-32) which can be utilized by controller 234. Ayre discloses that controller 234 receives the motor current value as an input to determine the blood flow of the system (see col. 17, ln. 8-14). Therefore, the Examiner takes the position that the controller 234 may detect backflow of blood in the system using the motor current value.

11. Regarding claim 2, Ayre discloses that algorithms are utilized to provide the flow rate detection (see col. 7, ln. 65-67 and Figure 39).

12. Regarding claim 16, Ayre discloses that the rotational speed of the rotor is controlled based on the detection of flow parameters (see col. 5, ln. 8-16).

13. Regarding claim 17, Ayre discloses that the rotor is an impeller that pumps blood by a centrifugal force through its rotation (see col. 8, ln. 23-24).

14. Regarding claim 18, Ayre discloses that the housing has inlet and outlet ports 6 and 7, respectively, a centrifugal pump section having a magnetic impeller, and a magnetic rotor, wherein the impeller is rotated in the housing by an electromagnetic torque (see col. 1, ln. 13-21).

15. Claims 1-3, 8, 9, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuhki et al. (*Artificial Organs* 23(6): 523-537), herein Yuhki. Regarding claim 1, Yuhki discloses a study performed to detect regurgitation in an implantable centrifugal pump. It is inherent that when an implantable centrifugal pump is used, the pump includes an inlet port, and outlet port, a rotor, and a motor. Further, Yuhki discloses utilizing a motor current value to detect backflow in the pump (see pg. 532, col. 2, ln. 14-18).

16. Regarding claim 2, one of the disclosed purposes of the study of Yuhki is to detect backflow without any direct flow rate detecting means (see Abstract, line 3).

17. Regarding claim 3, Yuhki discloses that the motor current value is used along with the threshold to determine if regurgitation has occurred, therefore Yuhki inherently utilizes a "motor current threshold storing or calculating section".

18. Regarding claim 8, Yuhki discloses a theoretical study in which a motor current frequency distribution calculation function is inherently used in order to calculate a frequency distribution of the motor current value in order to evaluate the presence of regurgitation (see pg. 533, col. 1, ln. 31-35 and col. 2, ln. 1-10).

19. Regarding claim 9, the Examiner interprets the claim to mean that regurgitation is detected if the intensity of a secondary harmonic is greater than or equal to a proportion of the fundamental wave. Yuhki discloses that regurgitation was detected when the amplitude of the secondary harmonic was 45% with respect to the fundamental wave (see pg. 534, col. 2, ln. 1-12). Therefore, when the proportion of the fundamental wave is less than or equal to 0.45, regurgitation is detected.

20. Regarding claim 16, the main focus of Yuhki's study was to optimize the speed at which a pump is operated while reducing regurgitation. Therefore, Yuhki inherently teaches increasing the rotational speed of the rotor when regurgitation is detected (see pg. 533, col. 2, ln. 29-30).

21. Regarding claim 17, the apparatus utilized by Yuhki is a centrifugal pump, therefore it is inherent that the rotor is an impeller which pumps blood by a centrifugal force.

***Claim Rejections - 35 USC § 103***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakazeki and Ayre in view of Hubbard et al. (U.S. Patent No. 4,778,445, cited by applicant), herein Hubbard. Nakazeki and Ayre each disclose the invention essentially as claimed but fail to disclose an alarm means for indicating when a backflow is detected. Hubbard discloses a centrifugal blood pump with detects backflow in a system and once detected, provides an alarm signal in order to indicate to an operator (patient or physician) that reverse flow has been detected in the system (see col. 2, ln. 25-29). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize a reverse flow alarm system, as taught by Hubbard, in



the inventions of Nakazeki and Ayre in order to alert an operator that reverse flow has been detected in the blood pump system.

***Allowable Subject Matter***

24. Claims 4-7 and 10-14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Reich et al. (U.S. Patent No. 6,623,420) which discloses a physiological heart pump control;

Kikugawa (*Artificial Organs* 25(9):703-708) which discloses using motor current waveforms to detect backflow in centrifugal blood pumps.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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